

APTIMA Assay for Neisseria gonorrhoeae - Expanded Indication: ThinPrep Specimens

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GEN-PROBE® APTIMA® Assay for Neisseria gonorrhoeae

General Information

Submitted By:

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Trade Name:

GEN-PROBE® APTIMA® Assay for Neisseria gonorrhoeae

Common or Usual Name:

rRNA target-amplified nucleic acid probe test for the in vitro

diagnostic detection of Neisseria gonorrhoeae

Classification Name:

DNA Reagents, Neisseria

Classification Code:

Medical Specialty: Microbiology

Product Code: LSL

Registration Number: CFR 866.3390

Device Class: 2

Description: Reagents used to identify Neisseria spp. directly from clinical specimens or cultured isolates derived from clinical specimens. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus Neisseria, such as epidemic cerebrospinal meningitis, meningococcal disease, and gonorrhea, and also provides epidemiological information on diseases caused by these microorganisms.

Substantially Equivalent Devices:

GEN-PROBE® APTIMA® Assay for Neisseria gonorrhoeae

Device Description

Clearance of this premarket notification extends the clinical performance claims of the commercially available GEN-PROBE APTIMA Assay for *Neisseria gonorrhoeae* to include PreservCyt liquid Pap specimens (collected and processed by the Cytyc ThinPrep 2000 Processor) as acceptable testing specimens. The ancillary kit formulated for this specific application is the commercially available GEN-PROBE APTIMA Specimen Transfer Kit. The components of the APTIMA Specimen Transfer Kit include: (1) a transport tube containing transport media with a penetrable cap and (2) specific instructions for use regarding decontamination and specimen processing procedures. The APTIMA Specimen Transfer Kit may only be used in conjunction with GEN-PROBE APTIMA Assays for the detection of *Chlamydia trachomatis* and/or *Neisseria gonorrhoeae*.

Intended Use

APTIMA Assay for Neisseria gonorrhoeae package insert:

The APTIMA® Assay for *Neisseria gonorrhoeae* is a target amplification nucleic acid probe test that utilizes target capture for the *in vitro* qualitative detection of ribosomal RNA (rRNA) from *Neisseria gonorrhoeae* (GC) to aid in the diagnosis of gonococcal urogenital disease. The assay may be used to test the following specimens from symptomatic individuals: clinician-collected endocervical, vaginal and male urethral swab specimens; and patient-collected female and male urine specimens. The assay may be used to test the following specimens from asymptomatic individuals: clinician-collected endocervical and vaginal swab specimens; and patient-collected vaginal swab specimens¹ and female and male urine specimens. The assay is also intended for use with the testing of gynecological specimens collected in the PreservCyt Solution and processed with the Cytyc ThinPrep 2000 System.

¹ Patient-collected vaginal swab specimens are an option for screening women when a pelvic exam is not otherwise indicated. The vaginal swab specimen collection kit is not for home use.

Ancillary Kit package insert:

The GEN-PROBE APTIMA Specimen Transfer Kit is only for use with GEN-PROBE APTIMA Assays for the detection of *Chlamydia trachomatis* and/or *Neisseria gonorrhoeae*. The GEN-PROBE APTIMA Specimen Transfer Kit allows for APTIMA Assay testing of gynecological specimens collected and processed by the Cytyc ThinPrep 2000 Processor according to the instructions provided.

APTIMA Assay for Neisseria gonorrhoeae

A complete description of the APTIMA Assay for *Neisseria gonorrhoeae* is provided in the commercialized package insert.

Summary of Non-Clinical (Analytical Laboratory) Performance Data

Limit of Detection (Analytical Sensitivity)

N. gonorrhoeae analytical sensitivity (limit of detection) was determined by directly comparing dilutions of 51 different clinical isolates in culture and in the APTIMA GC Assay. The analytical sensitivity claim for the assay is 50 cells/assay (362 cells/swab, 250 cells/mL urine, 487.5 cells/mL PreservCyt Solution liquid Pap).

Analytical Specificity

A total of 154 culture isolates were evaluated using the APTIMA GC Assay. These isolates included 86 organisms that may be isolated from the urogenital tract and 68 additional organisms that represent a phylogenetic cross-section of organisms. The tested organisms included bacteria, fungi, yeast, parasites and viruses. All organisms except *C. psittaci, C. pneumoniae, U. urealyticum* and the viruses were tested at 1.0×10^6 cells/assay in Kova-trol/urine transport media and 60 organisms were tested in swab transport media. *C. psittaci* VR601 was tested at 8×10^4 cells/assay and *C. psittaci* VR125 was tested at 1×10^5 cells/assay. *C. pneumoniae* was tested at 4×10^3 cells/assay and *U. urealyticum* was tested at 6.7×10^6 cells/assay. The viruses were tested as follows: (a) herpes simplex virus I: 2.5×10^4 TCID₅₀/assay, (b) herpes simplex virus II: 6.0×10^4 TCID₅₀/assay, (c) human papillomavirus $16: 2.9 \times 10^6$ DNA copies/assay and (d) cytomegalovirus: 4.8×10^5 cells/assay. The list of organisms tested is shown in Table 1.

Table 1: APTIMA GC Assay Analytical Specificity

Achromobacter verosis Acinetobacter calcoaceticus Acinetobacter logica Flovobacterium meningosepticum Acinetobacter lwoffi Acinetobacter lwoffi Fusobacterium nucleatum Neisseria sicaca (3) Actinomyces israelii Gardnerella vaginalis Neisseria pplyaaccharea Actinomyces pyogenes Gemella haemolysans Neisseria pplyaaccharea Aerococcus viridans Haemophilus ducreyi Paracoccus denitrificans Aeromonas hydrophila Hemophilus influenzae Peptostreptococcus anaerobius Peptostreptococcus Alcaligenes faecalis Bacillus subtilis Human papilloma virus I Pelsiomonas shigelloides Bacillus subtilis Bacteriodes fragilis Kingella dentrificans Proteus wiralis Bifidobacterium adolescentis Bifidobacterium dolescentis Bifidobacterium dolescentis Brevibacterium linens Lactobacillus personii Campylobacteri jimi Lactobacillus jensonii Rahnella catarrhalis Lactobacillus lactis Candida albicans Lactobacillus lactis Rhodospirillum rubrum Candida parapsilosis Leuconostoc paramenseneroides Candida propicalis Listeria monocytogenes Chlamydia psittaci (2) Moraxella lacunata Mycoplasma gentialium Corynebacterium gentialium Mycoplasma gentialium Streptococcus anilasse Cytomegalovirus N. meningitidis Serogroup A Streptococcus sanguis Enterobacter aceanii Neisseria dentrificans Neisseria providencia Neisseria flava Providencia sultiva (3) Vibrio parahaemolyticus Erwinia herbicola	ORGANISM	ORGANISM	ORGANISM
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	Erwinia herbicola		T. Sama Chief Ocollica
	Erysipelothrix rhusiopathiae	Neisseria lactamica (9)	

(n) = Number of strains tested

All organisms tested produced a negative result in the APTIMA GC Assay.

Interference Studies

The following interfering substances were individually spiked into swab, PreservCyt liquid Pap, and/or urine specimens: 10% blood, contraceptive jelly, spermicide, moisturizer, hemorrhoidal anesthetic, body oil, powder, anti-fungal cream, vaginal lubricants, feminine spray and leukocytes (1x10⁶ cells/mL). The following interfering substances were individually spiked into urine specimens: 30% blood, urine analytes, protein, glucose, ketones, bilirubin,

nitrate, urobilinogen, pH 4 (acidic), pH 9 (alkaline), leukocytes (1x10⁶ cells/mL), cellular debris, vitamins, minerals, acetaminophen, aspirin and ibuprofen. All were tested for potential assay interference in the absence and presence of GC at the estimated rRNA equivalent of 50 GC cells/assay (250 fg/assay). The rRNA equivalents were calculated based on the genome size and estimated DNA:RNA ratio/cell of each organism. No interference was observed with any of the tested substances. No inhibitors of amplification were observed in the APTIMA GC Assay.

Recovery

Escherichia coli, Gardnerella vaginalis, Lactobacillus acidophilus, Bacteroides ureolyticus and Staphylococcus epidermidis (1 x 10⁸ cells/assay) were added to samples containing the rRNA equivalent of approximately 50 N. gonorrhoeae cells (250 fg). These additions did not interfere with the amplification and detection of N. gonorrhoeae rRNA using the APTIMA GC Assay.

Liquid Pap Specimen Stability Studies

Data to support the recommended shipping and storage conditions for PreservCyt Solution liquid Pap samples were generated with negative processed and unprocessed liquid Pap samples. For the unprocessed samples, four pools of PreservCyt Solution samples were tested after being stored in the Cytyc PreservCyt Solution vial. Each specimen pool was spiked with 50-100 CFU GC/assay, held at 2°C, 10°C, and 30°C, then tested at baseline and on days 5, 7, 8, 14, 18, 21, 25 and 36. All of the spiked samples were positive for GC at all times and temperatures. For the processed samples, four pools of PreservCyt Solution samples were used to determine processed specimen stability at 2°C to 30°C. Each negative sample pool was spiked with 50-100 IFU GC/assay, then tested at baseline. Prior to processing, the PreservCyt Solution samples were stored at 30°C for seven (7) days to simulate the time lapse between sample collection, Pap processing and shipment to a microbiology testing lab. After seven days at 30°C, 1 mL aliquots of each pool were transferred to an APTIMA Specimen Transfer Tube and tested at baseline before being placed at 2°C, 10°C, and 30°C. The processed samples were then tested for 17 days stored at 30°C and 36 days stored at 2°C to 10°C. All of the spiked samples were positive for GC at all times and temperatures. Data to support longer storage conditions were generated from four pools of negative processed PreservCyt Solution samples tested at below freezing temperatures. Each pool was spiked with 50-100 IFU CT/assay, then tested at baseline. Each pool was first placed at 30°C for 14 days and then stored at -20°C or -70°C over the course of 106 days. All of the spiked samples were positive for GC at all times and temperatures.

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APTIMA Assay for Neisseria gonorrhoeae - Expanded Indication: ThinPrep Specimens

Precision

over a five-day period for 140 results at the 0.1, 0.5, and 50 CFU level. There were 136 valid results and 4 invalid results for the negative PreservCyt specimen within-laboratory precision with the APTIMA GC Assay was determined by spiking PreservCyt vials with 20 GC samples' titers. Each of the resulting Pap-STM samples was tested once in the APTIMA GC Assay. A total of five runs were performed ten unspiked vials were divided between two operators. The operators vortexed the vials and then transferred 14 aliquots (1.0 mL each) per vial into 14 APTIMA Transfer Tubes as per the APTIMA Specimen Transfer Kit package insert. The operators were blinded to the CFU per reaction) and unspiked PreservCyt vials were tested as positive and negative controls. Ten vials spiked at each CFU level and CFU per vial (0.1 CFU per reaction) and 100 GC CFU per vial (0.5 CFU per reaction). Vials containing 10,000 GC CFU per vial (50 control panel. The invalid results were due to a misplacement of a TTU in the Leader HC+. The results are summarized in Table 2.

Table 2: APTIMA GC Assay Within-laboratory Precision Data for PreservCyt Using a 4-Member Precision Panel Containing 0 to 500 CFU/mL GC Cells.

						,	Within-Operator	perator	Between-Day	ı-Day	Between- Operator	en- tor	Total	
Panel Member	CFU/mL PreservCyt	CFUirxn	۵	Agreed	% Agrmt.	RLU (x1000)	SD (x1000)	رد (%)	SD (x10 00)	ر (چ)	SD (x1000)	(%) CA	SD (x1000)	<u>چ</u> د
Ą	_	0.1	140	θ£	27.9	313.7	758.3	758.3 241.7	132.5	42.2	0:0	0.0	769.8 245.4	245.4
В	ۍ ک	0.5	140	113	80.7	1211.1	1031.3	85.2	169.8	14.0	150.4 12.4	12.4	1056.0 87.2	87.2
U	500	50	140	140	100	5636.8	220.7	3.0	135.7	2.4	0.0	0.0	259.1	4.6
0	0	0	136*	136	100	1.2	0.5	ĕZ	0	A.M	0.3	N/A	9.0	Α̈́Ν
There was	* There were from involve results due to a missional TTM in the Lander UC.	when dies to	100	* 41 1.1 P	1									

There were four invelor results due to a misplaced TTU in the Leader HC+.

Note: Variability from some factors may be numerically negative, which can occur if the variability due to those factors is small. When this occurs, the variability as measured with SD and %CV is set to zero (13). N.A = Not applicable for negative panel members. Operator = Run. Samples with discondant results were included in the signal variability analysis.

Summary of Clinical Performance Data

A prospective multi-center clinical study was conducted to evaluate the use of the PreservCyt transport medium (a component of the ThinPrep 2000 System) as an alternative medium for gynecological specimens for the detection of N. gonorrhoeae by the APTIMA GC Assay. One thousand six hundred forty-six (1,646) symptomatic and asymptomatic female subjects attending OB/GYN, family planning, public health, women's, and STD clinics were evaluated in the clinical study. Of the 1,646 evaluable subjects, 1,287 were asymptomatic subjects and 359 were symptomatic subjects (Table 3). Subjects were enrolled from sites with GC prevalence that ranged from 0.0% to 5.0%. Two specimens were collected from each eligible subject: one PreservCyt liquid Pap specimen and one endocervical swab specimen. PreservCyt liquid Pap specimens were collected with the spatula/cyto-brush or a broom-like brush cervical sampling device. The distribution of cervical sampling devices is summarized in Table 4 by specimen collection site and overall. PreservCyt liquid Pap specimens were processed in accordance with the ThinPrep 2000 Processor Operator's Manual and APTIMA Specimen Transfer Kit package insert. After processing the PreservCyt liquid Pap specimen with the ThinPrep 2000 Processor, the specimen was transferred into the APTIMA Specimen Transfer Kit for testing with the APTIMA GC Assay. Sensitivity and specificity of the APTIMA GC Assay in PreservCyt liquid Pap specimens were calculated by comparing results to the patient infected status. The algorithm included APTIMA Combo 2 Assay and APTIMA GC Assay results in endocervical swab specimens. Both reference NAATs were required to be positive to establish an infected patient status. At least one reference NAAT was required to be negative to establish a non-infected patient status. If an equivocal result was obtained from any one of the reference NAATs, the patient infected status was categorized as inconclusive; these specimens were not included in the sensitivity and specificity calculations. Table 4 shows the sensitivities and specificities of the APTIMA GC Assay by symptom status and overall. Overall sensitivity was 92.3% (12/13). In symptomatic and asymptomatic subjects, sensitivities were 100% (7/7) and 83.3% (5/6), respectively. Overall specificity was 99.8% (1630/1633). In symptomatic and asymptomatic subjects, specificities were 99.4% (350/352) and 99.9% (1280/1281), respectively. Table 5 shows the sensitivities and specificities of the APTIMA GC Assay by specimen collection site and overall. Sensitivities ranged from 80.0% to 100%. Specificities ranged from 99.0% to 100%.

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APTIMA Assay for Neisseria gonorrhoeae - Expanded Indication: ThinPrep Specimens

Table 3: Distribution of Cervical Sampling Device Used for PreservCyt Liquid Pap Specimens

	1		Clinical Co	Clinical Collection Site			
Cervical Sampling Device Used	-	2	3	4	\$	9	Total
Spatula/Cytobrush	O	124	475	287	29	364	1307
Broom-Type Device	100	0	0	Ū	240	Ū	340

Table 4: Performance of the APTIMA GC Assay in PreservCyt Liquid Pap Specimens by Symptom Status

	() () () () () () () ()						
	APTIMA GC PreservCyt Result	* ;*	+/-	-(+	/- -	Sensitivity (%) (95% CI)	Specificity (%) (95% CI)
	Positive	7	0	0	2		
Symptomatic	Negative	0	O	0	350	100 (7/7) (59.0 100)	99.4 (350/352) (98.0 ± 99.9)
	Total	2	0	0	352)) ; ; ;
	Positive	ů,	0	0	-		
Asymptomatic	Negative	1	0	ជ	1275	83.3 (5/6) (35.9 ± 99.6)	99.9 (1280/1281) /99.6100/
	Total	ę,	0	ĸ	1276		
	Positive	12	0	0	m		
All	Negative	1	0	ស	1625	92.3 (12/13) (64.0 ± 99.8)	99.8 (1630/1633) (99.5 ± 100)
	Total	13	0	5	1628		

+/+ = Positive endocervical swab specimen result in the APTIMA COMBO 2 Assay/Positive endocervical swab specimen result in the APTIMA GC Assay

+/- = Positive endocervical swab specimen result in the APTIMA COMBO 2 Assay/Negative andocervical swab specimen result in the APTIMA. GC Assay

-/+ = Negative endocervical swab specimen result in the APTIMA COMBO 2 Assay/Positive endocervical swab specimen result in the APTIMA GC Assay

-/- = Positive endocervical swab specimen result in the APTIMA COMBO 2 Assay/Positive endocervical swab specimen result in the APTIMA GC Assay

Table 5: Performance of the APTIMA GC Assay in PreservCyt Processed Liquid Pap Specimens by Collection Site

Site	APTIMA GC PreservCyt Result	+/+	+!-	-54	n/a	Prev (%)	Sensitivity (%) (95% C.L)	Specificity (%) (95% C.I.)	PPV(%)	NPV(%)
	Positive	5	0	0	0					
1	Negative	0	0	0	95	5.0	100 (5/5) (47.8 = 100)	100 (95/95) (96.2 – 100)	100	100
	Total	5	0	0	95		111.70 - 1004	(30.2 - 100)		
	Positive	1	0	0	0					
2	Negative	0	0	0	123	0.8	100 (1/1) (2.5 – 100)	100 (123/123) (97.0 – 100)	100	100
	Total	1	0	0	123		,	(01.0 m) (00)		
	Positive	4	0	0	0				-	
3	Negative	1	Ō	0	470	1.1	80.0 (4/5) (28.4 – 99.5)	100 (470/470) (99.2 – 100)	100	9 9.8
	Total	5	0	0	470		,==::	(1 1)		
	Positive	1	0	0	3		- 1 hard			
4	Negative	0	0	3	280	0.3	100 (1/1) (2.5 – 100)	99.0 (283/286) (97.0 – 99.8)	25.0	100
	Total	1	0	3	283		(#.w 190)	(37.0 - 85.0)		
	Positive	0	Û	Ü	0					
5	Negative	0	Û	0	297	0.0	N/A	100 (297/297) (98.8 – 100)	N/A	100
	Total	0	Ü	Ü	297			(30.0 = 100)		
	Positive	1	0	0	0	7151				
6	Negative	0	٥	2	360	0.3	100 (1/1) (2.5 – 100)	100 (362/362) (99.0 – 100)	100	100
	Total	1	0	2	360		(#.W == 100)	(sa.u – rou)		
	Positive	12	0	Ü	3		·			
ALL	Negative	1	Q	5	1625	0.8	92.3 (12/13) (64.0 – 99.8)	99.8 (1630/1633) (99.5 – 100)	80.0	99.9
	Total	13	0	5	1628		(43.4 - 54.0)	(22.0 100)		

N/A = not applicable

^{+/+ =} Positive endocervical swab specimen result in the APTIMA COMBO 2 Assay/Positive endocervical swab specimen result in the APTIMA GC Assay

^{*/- =} Positive endocervical swab specimen result in the APTIMA COMBO 2 Assay/Negative endocervical swab specimen result in the APTIMA GC Assay

^{-/+ =} Negative endocervical swab specimen result in the APTIMA COMBO 2 Assay/Positive endocervical swab specimen result in the APTIMA GC Assay

^{-/- =} Positive endocervical swab specimen result in the APTIMA COMBO 2 Assay/Positive endocervical swab specimen result in the APTIMA GC Assay

Table 6: PreservCyt Liquid Pap Specimen Analysis for Patient Infected Status

	Endocen	vical Swab	Sympto	om Status
Patient Infected Status	APTIMA COMBO 2 Assay	APTIMA GC Assay	Symptomatic	Asymptomatic
Incondusive	E	Р	0	1
Infected	Р	Р	7	6
Non-Infected	N	N	352	1276
Non-Infected	N	Р	0	5
Total			359	1288

Prevalence

The prevalence of GC in patient populations depends on risk factors such as age, gender, the presence of symptoms, the type of clinic, and the test method. A summary of the prevalence of GC in North America, for PreservCyt liquid Pap specimens on the APTIMA GC Assay is shown in Table 7

Table 7: Prevalence of *N. gonorrhoeae* by Clinical Site and Overall as Determined by APTIMA GC Assay Results Using PreservCyt Liquid Pap Specimens

Site	% (#posi	tive/#tested)
1	5.0	(5/100)
2	0.8	(1/124)
3	0.8	(4/475)
4	1.4	(4/287)
5	0.0	(0/297)
6	0.5	(2/364)
All	1.0	(16/1647)

Conclusions from Non-Clinical and Clinical Data

The non-clinical and clinical study results support the use of PreservCyt liquid Pap specimens collected and processed by the Cytyc ThinPrep 2000 Processor in the currently marketed GEN-PROBE APTIMA Assay for *Neisseria gonorrhoeae*. The currently marketed GEN-PROBE APTIMA Specimen Transfer Kit provides necessary materials and instructions to allow for the testing of PreservCyt liquid Pap specimens in the APTIMA GC Assay.

The results of the clinical study demonstrate reasonable evidence that when the APTIMA GC Assay and the APTIMA Specimen Transfer Kit are labeled as proposed, the APTIMA GC Assay continues to be safe and effective for its stated intended use.

Contraindications and Cautions

There are no contraindications or cautions.



Food and Drug Administration 2098 Gaither Road Rockville MD 20850

NOV - 7 2006

Mr. E. Joseph McMullen Associate Director, Regulatory Affairs Gen-Probe Incorporated 10210 Genetic Center Drive San Diego, CA 92121

Re:

k062440

Trade/Device Name: GEN-PROBE® APTIMA® Assay for Neisseria gonorrhoeae

Regulation Number: 21 CFR 866.3390

Regulation Name: Neisseria spp. direct serological test reagents

Regulatory Class: Class II

Product Code: LSL Dated: August 18, 2006 Received: August 21, 2006

Dear Mr. McMullen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240)276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.

Tally withour

Director

Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety

Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: (if known)			
(II KIIOWII)	K06	52440	
Device Name: Indications for Us	e:		ssay® for Neisseria gonorrhoeae
acid probe test that ribosomal RNA (regonococcal urogen from symptomatic urethral swab spe	nt utilizes targe RNA) from M nital disease. T e individuals: c cimens; and fe	et capture for t leisseria gonore The assay may t clinician-collect emale and male	the is a target amplification nucleic the in vitro qualitative detection of thoeae (GC) to aid in the diagnosis of the used to test the following specimens ted endocervical, vaginal and male to urine specimens. The assay may be
collected endocery swab specimens ¹ a for use with the te	vical and vaging and female and sting of gynecolints, collected	ial swab specin I male urine sp ological specim	ptomatic individuals: clinician- nens; and patient-collected vaginal ecimens. The assay is also intended ens, from both symptomatic and 'Cyt Solution and processed with the
¹ Patient-collected vagi otherwise indicated. T	nal swab specime he vaginal swab sp	ns are an option for pecimen collection	screening women when a pelvic exam is not kit is not for home use.
Prescription Use (Part 21 CFR 801 S		OR	Over-the-Counter Use(Part 21 CFR-801 Subpart C)
PLEASE DO NO		ELOW THIS L PAGE IF NEE	INE – CONTINUE ON ANOTHER CDED
Conc	urrence of CD	and	Device Evaluation (ODE)
	Office of In Evaluation a	Vitro Diagno and Safety	stic Device
	510(k)	K062440	